

January 10, 2000

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNGOS AVENUE  
SAN JUAN, P.R. 00901-3223**WARNING LETTER**  
SJN-00-06**Certified Mail**  
**Return Receipt Requested**

Mr Julio F. Mendez  
President  
Procesadora Campofresco, Inc.  
P.O. Box 755  
Santa Isabel, PR 00757

Dear Mr. Mendez

Investigators from this office of the Food and Drug Administration conducted an inspection at your firm on June 9 & 10, 1999. During that inspection, samples of juice products were collected and a FDA-483, Inspectional Observations form, was issued to a member of your staff. Our analysis of the samples and review of the reported inspection evidence reveals serious violations of the Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR) Part 101 – Food Labeling, as follows:

1. "Coloso Concord Grape Juice 100% Pure" and "Fruti Natural Concord Grape Juice 100% Grape Juice from Concentrate" are adulterated under section 402(b)(1) of the Act because the valuable constituent, grape juice, has been omitted from the products. Both products are labeled as grape juice, however, Brix analyses showed that they actually contain only about 75% juice.

2. These products are misbranded as follows:

**Coloso Concord Grape Juice 100%**

- a) "Coloso Concord Grape Juice 100% Pure" is misbranded under section 403(a)(1) and 403(i)(1) of the Act because the statement of identity is false and misleading. The product fails to meet the minimum Brix level of 16 degrees for 100% grape juice (21 CFR 101.30 (h)), therefore, if the Brix level is not met, the statement of identity (Coloso Concord Grape Juice 100% Pure) must include a qualifying term such as "drink".
- b) The term "from concentrate" must appear as part of the statement of identity of the "Coloso Concord Grape Juice 100% Pure" since the product is made from juice concentrate (21 CFR 102.33(g)(1)).

- c) The "Coloso Concord Grape Juice 100% Pure" is further misbranded under section 403(i)(2) because it is a food which purports to be a beverage containing fruit juice, but the label fails to bear a statement on the information panel of the total percentage of fruit juice contained in the food (21 CFR 101.30(a)).

Fruti Natural Concord Grape Juice 100% Grape Juice from Concentrate

- a) "Fruti Natural Concord Grape Juice 100% Grape Juice from Concentrate" is misbranded under section 403(a)(1) and 403(i)(1) of the Act because the statement of identity is false and misleading. The product fails to meet the minimum Brix level of 16 degrees for 100% grape juice (21 CFR 101.30 (h)), therefore, if the Brix level is not met, the statement of identity (Fruti Natural Concord Grape Juice 100% Grape Juice from Concentrate) must include a qualifying term such as "drink".
- b) The "Fruti Natural Concord Grape Juice 100% Grape Juice from Concentrate" is further misbranded because the percent juice declaration (100%) on the information panel is false and misleading since the product contains only about 75% juice.

Your grape juice products are also misbranded within the meaning of Section 403(a) because the nutritional panel information and format is not in accordance with 21 CFR 101.9 in that:

- Based on the information provided, the labeling of the "Coloso Concord Grape Juice 100% Pure" does not qualify for the simplified nutrition label format. Therefore, the nutrient "saturated fat," "cholesterol," "dietary fiber," "sugars," and "vitamin A" must be declared on the label (21 CFR 101.9(f)). Also, the nutritional facts panel bars separating the information are not the correct point size and the serving size of 6.67 is incorrect.
- The Fruti Natural Concord Grape Juice 100% information in the nutritional facts panel is not completely bilingual (refer to the heading and % Daily Value), there is no separating bar after the footnotes, and the name of each nutrient is not followed immediately by the quantitative amount.

We acknowledge receipt of letter dated June 21, 1999 from Ms. Victoria Cerame, QA & Regulatory Manager addressed to Investigator Marybet Lopez in which you notified this office of the voluntary recall you initiated in response to the inspectional observation concerning the low Brix specification used for the production of grape juice. That action and the diligence in which it was done are considered adequate. We also acknowledge the July 8, 1999 letter from Ms. Cerame regarding the completion of the recall in which she states that "there should be no product in the market at 12° Brix".

That letter also references an attached internal communication concerning several other juice products held in your warehouse that, because of labeling deficiencies identified by your staff, you decided not to sell to your customers. However, a significant amount of these juice products are identified in that communication as sold to your employees. We advise you that distribution of misbranded product is prohibited under the Act regardless if they are sold, or even given

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away, to your employees for their consumption. Distribution of a misbranded product is a prohibited act under section 301(k).

In addition, despite the recall of the grape juice lots manufactured at your plant, we found "Coloso" and "Fruti Natural" grape juice lots in the marketplace that are also in violation of the Act as described in items 1 and 2 above. We understand that those product lots were manufactured and distributed by Southwest Farmers, Inc., Lajas, PR before you acquired the rights over these juice brands from that company. Although at this time we don't have complete information as to the nature of the buy-out in terms of responsibilities, we believe that you should take an active role in determining if significant quantities of these products remain in commercial channels. We note that you took a first step in resolving this matter in a July 13, 1999 written communication to the Southwestern Farmers official. We would appreciate it if you keep us informed of this matter.

The above violations are not meant to be an all-inclusive list of deficiencies at your plant. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct and prevent the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Andres Toro, Compliance Officer at 466 Fernandez Juncos Avenue, Puerta de Tierra, San Juan, P.R. 00901. If you have any questions concerning the violations noted please contact the above named Compliance Officer at telephone number (787) 729-6894 ext. 2131.

Sincerely



Mildred R. Barber  
District Director

Co: Victoria Cerame  
QA & Regulatory Affairs Manager  
Procesadora Campofresco, Inc.  
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Santa Isabel, PR 00757